

AGENDA +
COMPENDIUM



AI IN GXP

Driving the 5.0 Evolution of
Manufacturing, Validation, and Beyond

SEPTEMBER 15-16, 2026 | **RALEIGH, NC**



Operationalize Compliance. Rethink Validation. Govern and Implement AI.

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Meet the Faculty Driving Industry Excellence

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Ahmed Al-Shehab
Senior Advisor
Aldren.ai



Bryan Ennis
Founder and Chief Quality Officer
SWARE



Anant Agrawal
Head of AI
CIMCON Software



Stephen R Ferrell
Chief Product Officer
Valkit.ai



Sahar Ahmed
AI Cloud System Engineer
Lockheed Martin



Yari Fontebasso, PhD
Principal, AI Governance & IT Compliance
Systema Solutions



Vivekram Apparsundaram
Head - CQV Practice
Zifo Technologies



Colby Ford
Owner, Principal Consultant
Tuple / The Cloud Genomics Company



Aarti Arora
Principal
RxT



Joe Ault
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Compliance Services
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Ganesan
VP CSV/CSA
PSC Biotech



Abhishek Bachchan
Associate Director,
IT Security,
Risk and Quality
Gilead



William Gargano
Group SVP, IT & Life Sciences,
RCM Life Sciences and IT



Diane Gates
CenPharma



Rosalind Beasley
Co-Founder & CEO
Genari AI



Dori Gonzalez-Acevedo
Founder & CEO
ProcellaRx



Randall Bugge
Director, Lab & Quality Systems IT
Legend Biotech



Tim Kirkelie
Co-Founder & COO
Genari AI



Stephen J Cook
Sr. Director, GRC CSO and Tech Operations
Global Digital & Tech
GSK



Loganathan Kumarasamy
MS, RAC, AIGP Global Head – Compliance Services
Zifo Technologies



Shelly LaPointe
Quality Systems Director
Stealth Startup



Dr. Wanxing Cui
MD, PhD, CABP(H)
Director, Cell Therapy Manufacturing Facility
MedStar Georgetown University Hospital



Rahul Mohandas
Chief Executive Officer
AccQsure Inc.

Meet the Faculty Driving Industry Excellence



Khaled Moussally
Executive Vice President,
Corporate Development
& Operations
Compliance Group



Kelly Roland
Co-Founder & COO
GenasysAi



Courtney Steele
Director of Product
Management
DeepHow



Robin Stolzberg
Global Head of QA
Sapio Sciences



Carolyn Troiano
Compliance & Quality
Authority Lead/ Advisor
RiskCortex Limited



Bhagirath Reddy
Venkamolla
Lead AI/ML Solution's
Engineering &
Architecture
Gilead



Gaurav Walia
VP of CSV/CSA/DI &
Digital Governance &
Local Equity Partner
PQE Group



Robert (Bob) Wherry
MSc, MS, VP,
AI Compliance,
QACV Consulting



Ganesh Muralidharan
Global Delivery Head
Vaisesika Systems Consulting

Ben O'Brien
Business Development
Partner
Phanero

Andy O'Connor
Executive Director
Phanero



Binesh Prabhakar
Founder
One Vector



Subhabrata Purakayastha
Associate Director and
Head of Enterprise GxP
IT Systems Quality
Incyte Corporation



Bharanitharan Rajendran
Chief Technology Officer
Validfor

7:45	Registration and Continental Breakfast
8:20	Chairperson's Opening Remarks
8:20 - 9:00 Keynote RED BIRD	Harness the Power: AI-Driven Decision-Making, Data Integrity, and Continuous Validation in Life Sciences <i>Real-world insights on governing and scaling AI as a strategic enabler across regulated systems, audit readiness, and patient safety</i> William Gargano, Group SVP, RCM Life Sciences and IT
9:00 - 10:00 All Industry Panel Discussion RED BIRD	From Idea to Proof of Concept: How Enterprises Pilot AI in GxP <i>A high-level look at how AI initiatives are framed, tested, and governed in regulated environments</i> Moderator: Dori Gonzalez-Acevedo, Founder & CEO, ProcellaRx Panelists: Tim Roy Kinkelie, Co-Founder & COO, Genari AI ; Gaurav Walia, VP of CSV/CSA/DI & Digital Governance & Local Equity Partner, PQE Group ; Anant Agrawal, Head of AI, CIMCON
10:00 - 10:20	Exhibitor Showroom and Networking Refreshment Break
10:20 - 11:00	Select Between Knowledge Exchange Sessions
Reducing Human Risk RED BIRD	Reducing Human Risk in GxP: Building Inspection-Ready AI Systems <i>AI as a Defensible Control in GxP</i> Bharanitharan Rajendran, Chief Technology Officer, Validfor
CAPA & Deviation Management INNOVATION	How AI Is Transforming Deviations and the Evolving Role of Quality <i>Reframe Quality from a compliance obligation into a continuous improvement engine</i> Diane Gates, CenPharma
11:10 - 11:50	Select Between Knowledge Exchange Sessions
GSK RED BIRD	Automating a Common Controls Framework – Lessons Learned Stephen J Cook , Sr. Director, GRC CSO and Tech Operations Global Digital & Tech, GSK
Observable AI INNOVATION	Trust Is Not a Framework: Building Observable, Evaluated AI Systems in GxP Rosalind Beasley, Co-Founder & CEO, Genari AI
12:00 - 12:40	Select Between Knowledge Exchange Sessions
Data Infrastructure RED BIRD (Virtual Speaker)	Building a Scalable, Governable Data Estate for AI <i>Ensure your data infrastructure supports GxP-grade integrity, traceability, and reuse for the agentic era</i> Shelly LaPointe, Quality Systems Director, Stealth Startup
AI Adoption Impact INNOVATION	From Investment to Impact: Selecting the Right Pilot to Accelerate AI Adoption, Safely <i>Selecting your first high-impact GxP AI pilot to maximize ROI.</i> Andy O'Connor, Executive Director, Phanero

12:50 - 1:30	Lunch & Learns - Choose Between:
IT Infrastructure TENTH & TERRACE	Automate GxP IT Monitoring to Minimize Downtime and Risk <i>Use intelligent infrastructure tools to detect, respond, and recover in real time</i> Ahmed Al-Shehab, Senior Consultant/Advisor, Aldren.ai
1:40 - 2:20	Select Between Knowledge Exchange Sessions
Auditing Methodology RED BIRD	Auditing Agentic AI: Challenges & Solutions Robert (Bob) Wherry, MSc, MS, VP, AI Compliance, QACV Consulting Kelly Roland, Co-Founder & COO, GenasysAi
Cross-Functional Collaboration INNOVATION	Unite IT, QA, and Manufacturing to Drive Intelligent GxP Operations <i>Break down silos to speed adoption and sustain compliance</i> Ganesh Muralidharan, Global Delivery Head, Vaisesika Systems Consulting
2:30 - 3:10	Select Between Knowledge Exchange Sessions
Acceptance Criteria RED BIRD	Defining Acceptance Criteria for AI Validation <i>How to make intelligent systems testable, defensible, and inspection-ready</i> Abhishek Bachchan, Associate Director, IT Security, Risk and Quality, Gilead
LLM Adoption INNOVATION	From Proof of Concept to Practice: Large Language Models <i>How early LLM pilots evolved into repeatable capabilities and what we learned along the way</i> Colby Ford, Owner, Principal Consultant, Tuple / The Cloud Genomics Company
3:10 - 4:10	Speed Networking and Refreshment Break

4:10-4:50	Select Between Knowledge Exchange Sessions
Validation Documentation RED BIRD	Accelerate Validation Documentation with GenAI Assistants <i>Reduce burden in test scripts, SOPs, and reports while staying audit-ready</i> Rosalind Beasley, Co-Founder & CEO, Genari AI Inc.
AI Governance Pathways INNOVATION	"Intended Use" as the Corporate Governance Foundation for GxP AI. <i>Establishing "Intended Use" as the Corporate Governance Anchor for GxP AI</i> Ben O'Brien, Business Development Partner, Phanero
5:00-5:40	Select Between Knowledge Exchange Sessions
Digital Quality Metrics RED BIRD	Turn Quality Metrics into Action with Predictive Dashboards <i>Enable real-time decisions through smart indicators and trending analysis</i> Gaurav Walia, VP of CSV/CSA/DI & Digital Governance & Local Equity Partner, PQE Group
Cleaning Validation INNOVATION	Automate Cleaning Verification and MACO Analysis <i>Use AI models to support control strategies, alerts, and cleaning risk insights</i> Rahul Mohandas, Chief Executive Officer, AccQsure Inc.
5:45-6:45	Networking Cocktail Reception

8:00 - 8:20	Exhibitor Showroom Opens and Lite Breakfast
8:20 - 9:00	Select Between Knowledge Exchange Sessions
Tribal Knowledge RED BIRD	Capture Tribal Knowledge with AI-Driven Learning Systems: <i>Keep institutional insights accessible and adaptable as teams evolve</i> Ahmed Al-Shehab, Senior Consultant/Advisor, Aldren.ai
Human-Speed Validation INNOVATION	AI-Enabled Validation at the Speed of Humans in the Loop: The Capacity Constraint No One Is Talking About <i>The biggest barrier to AI-enabled validation isn't technology, it's the human in the loop capacity constraint</i> Anant Agrawal, Head of AI, CIMCON Software
9:10 - 9:50	Select Between Knowledge Exchange Sessions
Global Regulatory Strategy RED BIRD	Align Intelligent Systems with FDA, EMA, and Annex 11/22 Expectations <i>What inspectors will expect from your AI, validation, and documentation programs</i> Gaurav Walia, VP of CSV/CSA/DI & Digital Governance & Local Equity Partner, PQE Group
Expert Panel INNOVATION	Expert panel discussion: AI, digital transformation, and the future of the modern laboratory Moderator: Abhishek Bachchan, Associate Director, IT Security, Risk and Quality, Gilead Panelists: Steve Ferrell, Chief Product Officer, Valkit.ai ; Madhavi Ganesan, Vice President, PSC Biotech ; Joe Ault, Senior Manager Compliance Services, Thermo Fisher Scientific
10:10 - 10:40	Select Between Knowledge Exchange Sessions
Internal Audits + Document Review RED BIRD	Using AI to Modernize Internal Audits and Document Review <i>Practical approaches to applying AI across quality documents, audit preparation, and continuous compliance</i> Vivekram Apparsundaram, Head - CQV Practice, Zifo Technologies.
AI Validation Insights INNOVATION	One Size Doesn't Fit All: Real Lessons on AI, Digital Validation Tools, and Different GxP Technologies <i>applying AI-enabled Digital Validation Tools across CSV and CQV</i> Ganesan, VP CSV/CSA, PSC Biotech Randall Bugge, Director, Lab & Quality Systems IT, Legend Biotech
10:40 - 11:00	Exhibitor Showroom and Networking Refreshment Break
11:00 - 11:40 Quality and Compliance RED BIRD	10 Steps to Achieving AI Regulatory Compliance Robert (Bob) Wherry, MSc, MS, VP, AI Compliance, QACV Consulting
11:00 - 11:40 Validation Documentation INNOVATION	Validation Documentation as Code. Your Codebase Dosen't Drift. Why Does Your Validation Package? Anant Agrawal, Head of AI, CIMCON

11:00 - 11:40	Select Between Knowledge Exchange Sessions
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11:50 - 12:30	Select Between Knowledge Exchange Sessions
AI in GxP Practice RED BIRD	AI GxP Practice: What's Working, What's Not, and What We Should Do Differently <i>Quick Implementation wins, avoid missteps, and understand third-party risk realities</i> Binesh Prabhakar, Founder, One Vector
Navigating Life Sciences INNOVATION	Navigating the build vs buy decision in Life Sciences Stephen R. Ferrell, Chief Product Officer, Valkit.ai
12:40 - 1:20	Lunch and Learn
Qualify Cloud Platforms RED BIRD (Virtual Speaker)	Qualifying SaaS and IaaS for AI-Enabled Systems <i>Applying scalable, risk-based approaches to dynamic cloud environments</i> Sahar Ahmed, AI Cloud System Engineer, Lockheed Martin
Audit Trail Automation	Architecting AI-Driven Audit Trail Review for Continuous Compliance <i>From Static logs to active intelligence: Move beyond verification and towards insight</i> Khaled Moussally, Executive Vice President, Corporate Development & Operations, Compliance Group ; Elizabeth Prager – Product Specialist, Compliance Group ; Doug Lowman - IT Quality Industry Lead, Compliance Group
1:30 - 2:10	Select Between Knowledge Exchange Sessions
Workshop PART 1 RED BIRD	From Strategy to Execution: Implementing AI Across Validation, Laboratory, and Manufacturing GxP Environments William Gargano Group SVP, IT & Life Sciences, RCM Data & Solutions
Continuous Validation INNOVATION	Establish Continuous Validation Through Real-Time Monitoring <i>Move beyond snapshots and toward constant assurance using smart tools</i> Carolyn Troiano, Compliance & Quality Authority Lead/Advisor, RiskCortex Limited

2:20 - 3:00	Select Between Knowledge Exchange Sessions
Workshop PART 2 RED BIRD	From Strategy to Execution: Implementing AI Across Validation, Laboratory, and Manufacturing GxP Environments William Gargano Group SVP, IT & Life Sciences, RCM Data & Solutions
Clinical Operations & Digital Health INNOVATION	Minimum Viable Product (MVP) for AI in GxP <i>Defining the smallest inspection-ready AI product across clinical trials and digital health – balancing governance, supplier risk, privacy, and real-world value</i> Bryan Ennis, Founder and Chief Quality Officer, SWARE ; Robin Stolzberg, Global Head of QA, Sapio Sciences ; Courtney Steele, - Director of Product Management, DeepHow
3:00 - 3:20	Exhibitor Showroom and Refreshment Break
3:20 - 4:00	Select Between Knowledge Exchange Sessions
Inspection Readiness RED BIRD	Learning from Enforcement: Using AI to Improve Inspection Readiness Dr. Wanxing Cui, MD, PhD, CABP(H) Director, Cell Therapy Manufacturing Facility, MedStar Georgetown University Hospital
Cybersecurity & Authentication INNOVATION	Strengthening AI Systems with Built-In Cybersecurity and Access Control <i>Governance, security, and access controls for AI-enabled environments</i> Aarti Arora, Principal, RxT
4:10 - 4:50	Select Between Knowledge Exchange Sessions
Installation Validation RED BIRD	<u>From Installation to Validation:</u> <u>Testing Local AI Against GxP Requirements</u> Benchmarking open-source language models on regulated data — without the cloud, the vendor, or the budget Yari Fontebasso, PhD, Principal, AI Governance & IT Compliance, Systema Solutions
Data Lakes INNOVATION	Designing AI-Ready Data Lakes for GxP: Architecture, Governance, and Scale <i>Integrating enterprise and manufacturing data to support compliant, insight-driven AI initiative</i> Bhagirath Reddy Venkamolla, Lead AI/ML Solution's Engineering & Architecture, Gilead Loganathan Kumarasamy, MS, RAC, AIGP Global Head – Compliance Services, Zifo Technologies
5:45	Closing Remarks